UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, ET AL.,

Plaintiffs,

v. **No. 4:22-cv-0915-P**

FOOD AND DRUG ADMINISTRATION,

Defendant.

ORDER

In May 2023, the Court ordered the Food and Drug Administration ("FDA") to produce all documents related to the approval of Pfizer's 12 to 15-year-olds COVID-19 vaccine and Moderna's adult COVID-19 vaccine by **June 30, 2025**. The Court also ordered the Parties to meet and confer about a mutually acceptable production schedule of those documents—roughly 4.5 million documents in total. But the Parties failed to agree on a production schedule and submitted dueling schedules for this Court's consideration. Having considered the Parties proposed production schedules, arguments in support, and applicable law, the Court **ORDERS** the following:

1. The FDA must produce all documents related to Pfizer's 12 to 15-year-olds COVID-19 vaccine by **January 2, 2024**, on a rolling basis at a rate no fewer than (1) 35,000 pages per month in July, August, and September 2023, (2) 55,000 pages per month in October and November 2023, and (3) 180,000 pages per month thereafter.
2. The FDA must produce all documents related to Moderna's adult COVID-19 vaccine by **June 30, 2025**, at a rate no less than 75,000 pages per month in January 2024 and 180,000 pages per month thereafter.
3. The FDA's rolling productions are due on the first business day of each month.

4. The FDA can "bank" any processed pages it produces in excess of its monthly quota.
5. If the FDA asserts any privilege, exemption, or exclusion as to any responsive record or portion of it, the FDA must—concurrent with each production required by this Order—produce a redacted version of the record, redacting only those portions to which the privilege, exemption, or exclusion is asserted.
6. The Parties must submit a Joint Status Report detailing the progress of the rolling production by **September 1, 2023**, and every **90 days** thereafter.

The chart below illustrates the minimum rate of production for the two vaccines mentioned above and Pfizer's 16+ COVID-19 vaccine[1] based on the expected number of documents set to be produced:

Minimum # of Documents to be Produced

	Pfizer's 16+ Vaccine	**Pfizer's 12-15 Vaccine**	**Moderna's Adult Vaccine**	**Total**
July 3, 2023	55,000	35,000	0	90,000
Aug. 1, 2023	55,000	35,000	0	90,000
Sept. 1, 2023	55,000	35,000	0	90,000
Oct. 2, 2023	55,000	55,000	0	110,000
Nov. 1, 2023	55,000	55,000	0	110,000
Dec. 1, 2023	0[2]	180,000	0	180,000
Jan. 2, 2024	0	105,000[3]	75,000	180,000
Feb. 1, 2024	0	0	180,000	180,000
1st business day of every month thereafter	0	0	180,000	180,000

[1] *See Pub. Health & Med. Pros. for Transparency v. FDA*, No. 4:21-CV-1058-P, 2022 WL 90237 (N.D. Tex. Jan. 6, 2022) (Pittman, J.).

[2] This assumes that all documents related to Pfizer's 16+ vaccine have been produced. If not, the FDA must continue to produce at least 55,000 pages per month until completion.

[3] This number reflects the expected number of documents remaining at that time. All documents—regardless of the actual number remaining at that time—must be produced by January 2, 2024.

SO ORDERED on this **12th day** of **June 2023**.

Mark T. Pittman
UNITED STATES DISTRICT JUDGE